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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,860	11/28/2000	Andrew Welcher	99,372-A	9408

20306 7590 05/16/2002

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/16/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,860

Applicant(s)

WELCHER ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 9, 12-42 and 46-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 25 February 2002 is acknowledged. Claims 1-56 are pending in this application. Applicant's statement that claims 1-8, 10, 11, and 43-45 were indicated by the Examiner to be pending is incorrect; these claims are under examination. Claims 9, 12-42, and 46-56 have not been cancelled but are withdrawn from consideration as drawn to a non-elected invention.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The objection to the specification is withdrawn in response to Applicant's amendment.
3. The rejection of claims 1-8, 10, 11, and 43-45 under 35 U.S.C. 101 as lacking utility is withdrawn in response to Applicant's provision of post-filing date art that supports the asserted utility.
4. The corresponding rejection of claims 1-8, 10, 11, and 43-45 under 35 U.S.C. 112, first paragraph, as lacking enablement because the invention lacks utility is withdrawn for the reasons set forth above.
5. The rejection of claims 1, 2, 4-8, 10, 11, and 43-45 under 35 U.S.C. 112, first paragraph, as lacking written description due to deficiencies in the deposit information is withdrawn in response to Applicant's submission of a signed declaration.

Claim Rejections Maintained/New Grounds of Rejection

6. The rejection of claims 1-8, 10, 11, 43, and 45 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate with the scope of the claims is maintained.

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Applicant argues that one of ordinary skill in the art would know how to make and use the claimed variants and fragments. Applicant argues that the recitation of a functional feature coupled with the teachings in the specification of the preparation of variants having conservative substitutions, as well as appropriate hybridization conditions, would allow the identification of variants and fragments having an activity of the polypeptide.

Applicant's arguments have been fully considered but have not been found to be persuasive. Applicant's example of moderate hybridization allows a 21% mismatch; further, there is no limiting definition of moderate conditions (see below). The claims also encompass molecules of only 70% identity, and sequences comprising fragments of only 25 amino acids, with the limitation only that the peptide have "an activity"^{OR} ~~of~~ be "antigenic". They also encompass sequences having an unlimited number of substitutions, insertions, modifications, and truncations. Furthermore, the required "activity" is not limited to any particular activity; there is no definition of "an activity of the polypeptide" (see below). In addition, tyrosine phosphorylation of cellular proteins occurs in response to many different stimuli; requirement of "phosphorylation activity" would not provide any particular functional limitation. The claims thus encompass molecules that are widely varying in length, composition, and potential function. Applicant has taught only one activity for one polypeptide; one of skill in the art would be unable to predict which, if any, peptides of only 25 amino acids would have this or any activity. Applicant has provided no guidance to indicate that a peptide that small would be functional. One of skill would further be unable to predict which, if any, variants having only limited homology would function as interferons or have any function at all. A single amino acid change can turn an agonist into an antagonist; Applicant has not taught what residues are required for

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function and one of skill in the art would not be able to predict which could be altered and which could not be. Thus, since the claims are broadly drawn to encompass molecules of widely variant structure, since the required "activity" is not limited to any particular activity, and since the specification provides no guidance as to what residues or regions are required for function, it would require undue experimentation for one of skill in the art to make and use the invention as broadly claimed.

7. The rejection of claims 1-8, 10, 11, and 43-45 under 35 U.S.C. 112, first paragraph, as lacking written description is maintained.

Applicant argues that "phosphorylation activity" is a functional feature of the claimed genus. Applicant further argues that conservative amino acid substitutions may be made in non-conserved regions. Applicant contends that sufficient written description has been provided.

Applicant's arguments have been fully considered but have not been found to be persuasive. The claims are drawn to molecules having an "activity", not a phosphorylation activity. There is no definition of what that activity might be. Further, there is no definition of a "phosphorylation activity"; what is shown in example 5 on p. 103 is that "several proteins showed an increase in cellular protein phosphorylation" as determined by an anti-phosphotyrosine antibody. Such an activity is not specific to any particular molecule or class of molecules; many different proteins that are both structurally and functionally unrelated to each other and to interferons exhibit such an activity. Thus "phosphorylation activity" is not an activity that defines a genus of interferon-like molecules. Additionally, while homologous regions are identified, the claims are not limited to variants in any particular region. Thus, since there are no required structures and no particular required activity, and since the one activity

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described is not specific to any class of proteins, one of skill in the art would not conclude that Applicant has described the genus of interferon-like molecules, including fragments and variants.

8. The rejection of claims 1-8, 10, 11, and 43-45 under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of hybridization conditions, and of claims 2-8, 10, 11, and 43-45 as indefinite in the recitation of "an activity of the polypeptide" is maintained.

Applicant argues that hybridization conditions are defined on pages 17 and 18. Applicant argues that the claims encompass only molecules that possess "an inherent activity (phosphorylation)". Applicant argues that the expression of the mRNA teaches that the polypeptide has an inherent function. Applicant argues that the specification teaches that the polypeptide has phosphorylation activity. Applicant concludes that the term is not indefinite.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated in the previous office action, hybridization conditions are not in fact defined. Only examples are provided. There are no conditions that are specifically included or excluded; there are no limitations on what is considered stringent or moderately stringent and what is not. Thus one of skill in the art would not be able to determine what conditions, and thus what molecules, were and were not encompassed by Applicant's claims.

Applicant's specification further does not provide a limiting definition of "an activity of the polypeptide". There is no definition of what activities the polypeptide has. All that is provided is evidence of tyrosine phosphorylation of cellular proteins. The claims are not limited to this activity but require merely "an activity". Thus, since one of skill in the art would not know what activities were encompassed, one of skill in the art would not know what molecules were encompassed. Limitation of the claims to "phosphorylation activity" would not overcome

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this rejection; there is no definition of "phosphorylation activity". There is no requirement that any particular proteins, such as those noted by Applicant, be phosphorylated. Thus "phosphorylation activity" would not be sufficient to define the activity of polypeptides encoded by the claimed invention so that one of skill in the art would know what molecules Applicant intended to claim.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
May 13, 2002

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above the printed name and title.

LORRAINE SPECTOR
PRIMARY EXAMINER